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| APPLICATION NO. | FI | LING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|------------------|------------|----------------------|-------------------------|------------------|
| 09/991,225 | 1,225 11/16/2001 | | John N. Feder | D0075 NP | 3953 |
| 23914 | 7590 | 07/16/2003 | | | |
| STEPHEN I | | - | EXAMINER | | |
| BRISTOL-MYERS SQUIBB COMPANY PATENT DEPARTMENT | | | | ULM, JOHN D | |
| P O BOX 4000 PRINCETON, NJ 08543-4000 | | | | ART UNIT | PAPER NUMBER |
| | | | | 1646 | 0 |
| | | | | DATE MAILED: 07/16/2003 | 7 |

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No. 09/991,225

Applicant(s)

Examiner

Feder et al.

John Ulm

Art Unit 1646



| The MAILING DATE of this communication appear | rs on the cover sheet with the correspondence address | | | | | |
|---|---|--|--|--|--|--|
| Period for Reply | | | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SE THE MAILING DATE OF THIS COMMUNICATION. | | | | | | |
| Extensions of time may be available under the provisions of 37 CFR 1.136 (a). mailing date of this communication. | | | | | | |
| If the period for reply specified above is less than thirty (30) days, a reply within If NO period for reply is specified above, the maximum statutory period will apply Failure to reply within the set or extended period for reply will, by statute, cause Any reply received by the Office later than three months after the mailing date of earned patent term adjustment. See 37 CFR 1.704(b). | y and will expire SIX (6) MONTHS from the mailing date of this communication. the application to become ABANDONED (35 U.S.C. § 133). | | | | | |
| Status | | | | | | |
| | | | | | | |
| 2a) ☐ This action is FINAL . 2b) ☑ This ac | | | | | | |
| closed in accordance with the practice under $Ex p$ | except for formal matters, prosecution as to the merits is earte Quayle, 1935 C.D. 11; 453 O.G. 213. | | | | | |
| Disposition of Claims | | | | | | |
| 4) 💢 Claim(s) <u>1-41</u> | is/are pending in the application. | | | | | |
| | is/are withdrawn from consideration. | | | | | |
| 5) Claim(s) | is/are allowed. | | | | | |
| 6) Claim(s) | | | | | | |
| 7) | | | | | | |
| | are subject to restriction and/or election requirement. | | | | | |
| Application Papers | | | | | | |
| 9) \square The specification is objected to by the Examiner. | | | | | | |
| 10) The drawing(s) filed onis/arc | e a) \square accepted or b) \square objected to by the Examiner. | | | | | |
| | drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | |
| | is: a) approved b) disapproved by the Examiner. | | | | | |
| If approved, corrected drawings are required in reply | | | | | | |
| 12) \square The oath or declaration is objected to by the Exam | niner. | | | | | |
| Priority under 35 U.S.C. §§ 119 and 120 | | | | | | |
| 13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). | | | | | | |
| a) □ All b) □ Some* c) □ None of: | | | | | | |
| 1. Certified copies of the priority documents have | | | | | | |
| 2. Certified copies of the priority documents have | | | | | | |
| application from the international Bure | documents have been received in this National Stage eau (PCT Rule 17.2(a)). | | | | | |
| *See the attached detailed Office action for a list of th | | | | | | |
| 14) Acknowledgement is made of a claim for domestic | | | | | | |
| a) The translation of the foreign language provisional application has been received. | | | | | | |
| 15) Acknowledgement is made of a claim for domestic | priority under 35 U.S.C. §§ 120 and/or 121. | | | | | |
| Attachment(s) | | | | | | |
| Notice of References Cited (PTO-892) Notice of Dreftenerson's Petent Drawing Position (PTO 049) | 4) Interview Summary (PTO-413) Paper No(s). | | | | | |
| 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) | 5) Notice of Informal Patent Application (PTO-152) | | | | | |
| 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) | | | | | | |

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Claims 1 to 41 are pending in the instant application.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1 to 10, 14, 15, 21, 22 and 27 to 32, drawn to an isolated nucleic acid, vector, host cell and method of use, classified in class 435, subclass 69.1.
- II. Claims 11, 12, 16, 20 and 33 to 35, drawn to an isolated polypeptide and method of use, classified in class 530, subclass 350.
- III. Claim 13, drawn to an antibody, classified in class 530, subclass 388.22.
- IV. Claim 17, in so far as it is drawn to a method of treatment by administering a receptor polypeptide, classified in class 514, subclass 2.
- V. Claim 17, in so far as it is drawn to a method of treatment by administering a recombinant nucleic acid encoding a receptor protein, classified in class 514, subclass 44.
- VI. Claim 18, drawn to a method of genetic analysis, classified in class 435, subclass 6.
- VII. Claim 19, drawn to an immunoassay, classified in class 436, subclass 536.
- VIII. Claim 23, drawn to a product of unspecified constitution, classification undeterminable.
- IX. Claims 24 and 25, drawn to a method of molecular mutagenesis, classified in class 435, subclass 71.3.
- X. Claim 26, drawn to a polynucleotide of unspecified structure or function, classified in class 536, subclass 23.5.

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- XI. Claim 36, drawn to a cell comprising the reporter gene NFAT/CRE and a specified polypeptide, classified in class 435, subclass 320.1.
- XII. Claim 37, drawn to a cell comprising a specific Gα protein and a specified polypeptide, classified in class 435, subclass 1.1.

XIII. Claims 38 to 41, drawn to a binding assay, classified in class 436, subclass 501. The inventions are distinct, each from the other because:

The "isolated" nucleic acid that is invention I, the "isolated" protein that is invention II, the antibody that is invention III, the product of unspecified constitution that is invention VIII, the polynucleotide of unspecified structure or function that is invention X, the cell comprising the reporter gene NFAT/CRE and a specified polypeptide that is invention XI and the cell comprising a specific Gα protein and a specified polypeptide that is invention XII are seven structurally and functionally different chemical compositions each of which can be made and used without any one or more of the other compounds. Lack of unity is shown because these seven different compositions lack a common utility which is based upon a common structural feature or combination of features lacking from the prior art and which has been identified as the basis for that common utility. For example, inventions XI and XII, as claimed, encompass cells which naturally express the polypeptide of invention II and, therefore do not require the isolated nucleic acid of invention I or the isolated protein of invention II.

Inventions II and IV are as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as

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claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed could be used in a process that is materially different from the claimed process of treatment, such as in a binding assay to identify ligands thereto or as an immunogen for the production of the antibody of invention III.

Invention I is related to each of inventions V, VI, IX and XIII as product and process of use. They are shown to be distinct because the method of treatment that in invention V, the diagnostic method of invention VI, the mutagenesis method of invention IX and the binding assay of invention XIII are four materially different methods of using the isolated nucleic acid of invention I as shown by the fact these four methods achieve different objectives by employing different method steps and different modes of operation. Further, the method of invention XIII does not require the isolated nucleic acid of invention I or the isolated protein of invention II because it can employ a cell which naturally expresses the polypeptide of invention II.

Inventions III and VII are related as product and process of use. They are shown to be distinct because the antibody of invention III can be used to produce the isolated protein of invention II, which is a process that is materially different from the diagnostic process of invention VII.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

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Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (703) 308-4008. The examiner can normally be reached on Monday through Friday from 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4242 or (703) 872-9306. Official responses under 37 C.F.R. § 1.116 should be directed to (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

JOHN ULM PRIMARY EXAMINER GROUP 1800